510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

A.	Company Name:	Triage Medical, Inc
B.	Company Address:	13700 Alton Parkway Suite 160 Irvine, CA 92618
C.	Company Phone:	(949) 472-0006
D.	Company Facsimile:	(949) 472-0016
E.	Contact Person:	Gayle Hirota Manager, Quality Assurance & Regulatory Affairs

DEVICE IDENTIFICATION

A.	Trade Name:	BONE-LOK® MVP Cortical-Cancellous Compression Device
B.	Catalog Number:	TMCD-35-1520S to TMCD-35-4050S TMCD-45-3040S to TMCD-45-6070S
C.	Common Name:	Bone Fixation Screw
D.	Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener
E.	Product Code:	HWC
F.	Device Panel:	Orthopaedic
G.	Device Class:	Class II (per 21 CFR 888.3040)

IDENTIFICATION OF MODIFIED DEVICE

The BONE-LOK® MVP Cortical-Cancellous Compression Device is similar in basic design and intended use to the Triage Medical Helical Compression Anchor System, Cannulated, Version 2 cleared under 510(k) K013903. The device modification includes devices fabricated from Titanium 6Al-4V alloy, which meets the requirements of ASTM F-136.

DEVICE DESCRIPTION

The BONE-LOK® MVP Cortical-Cancellous Compression Device is a double-helix screw with a compression-locking collar. It is available as 3.5mm or 4.5mm diameter device and is obtainable in various length ranges. The BONE-LOK® MVP Cortical-Cancellous Compression Device is intended for single use only.

Devices provided "STERILE" are double-pouched in Tyvek®/film pouches and sterilized by gamma radiation.

INTENDED USE

The BONE-LOK® MVP Cortical-Cancellous Compression Device is indicated for use in the general management of fractures and reconstructive surgery.

TECHNOLOGICAL CHARACTERISTICS

The BONE-LOK® MVP Cortical-Cancellous Compression Device is similar in basic design, construction and mechanical performance to the previously cleared Helical Compression Anchor System, Cannulated, Version 2. The device modification includes devices fabricated from titanium alloy in addition to devices fabricated from stainless steel alloy.

BIOCOMPATIBILITY AND PERFORMANCE DATA

The materials the BONE-LOK® MVP Cortical-Cancellous Compression Device are made from meet the requirements of ASTM F-138 (stainless steel) or ASTM F-136 (titanium). These materials are currently being utilized in a myriad of legally marketed orthopedic devices. Because the inertness and biocompatibility of these materials have already been established, additional testing is not required.

Performance test results indicate that the device is safe and satisfies functional performance requirements when used as indicated.

CONCLUSIONS DRAWN FROM STUDIES

The test results demonstrate that the modified BONE-LOK® MVP Cortical-Cancellous Compression Device is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Ms. Gayle Hirota
Manager, Quality Assurance and Regulatory Affairs
Triage Medical, Inc.
13700 Alton Parkway
Irvine, California 92618

Re: K042244
Trade/Device Name: BONE-LOK® MVP Cortical-Cancellous Compression Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 16, 2004
Received: August 19, 2004

Dear Ms. Hirota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1.6 **INDICATIONS FOR USE FORM**

Indications for Use

510(k) Number (if known):

Device Name: BONE-LOK® MVP Cortical-Cancellous Compression Device

Indications For Use: The BONE-LOK® MVP Cortical-Cancellous Compression Device is indicated for use in the general management of fractures and reconstructive surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042244